EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-02

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-030	06/01/2010 To 05/31/2014 Base Option Period Number 3	Reg. Determination 3/CCL4

Contractor: TOXSERVICES LLC

Specify Section and paragraph of Contract SOW: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/01/2013 To 05/31/2014

Comments:

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) [ ]

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/01/2010 To 05/31/2014		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Joyce Donohue (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1098 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT # 3-02

WORK ASSIGNMENT: **Regulatory Determination 3/CCL4**

WORK ASSIGNMENT MANAGER (WAM):

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Use Address below:
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OW/OST/HECD (4304-T)
EPA West-Connecting Wing, Room 5233MM
1301 Constitution Avenue, NW
Washington, DC 20460

PERIOD OF PERFORMANCE: June 1, 2013 through May 31, 2014

SOW TASKS: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

BACKGROUND

The Safe Drinking Water Act, as amended in 1996 (SDWA) requires EPA to publish a Contaminant Candidate List (CCL) of chemicals that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. SDWA also directs EPA to determine whether to regulate at least five contaminants from the CCL every five years; this is known as the Regulatory Determination process. The Agency must publish a Maximum Contaminant Level Goal (MCLG) and promulgate an NPDWR for a contaminant if the Administrator determines that the following three statutory criteria are met:

- The contaminant may have an adverse effect on the health of persons,
- The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern, and
- Regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

The ~~It should be noted that the~~ Regulatory Determination Process includes notice and an opportunity for public comment but is not a rulemaking.

This work assignment ~~was initiated in the Base period and has been rolled over to Option Period 1, 2, and now 3 to~~ is to continue the support for the Regulatory Determination effort and to add the capability to support the issuing of CCL4 as the agency prepares to publish the Federal Register Notice and supporting documents for each effort. ~~Some of activities associated with the Tasks below will be funded at this time and others may be funded by an amendment as their LOE requirements become better defined.~~

The regulatory process is an activity of the Office of Groundwater and Drinking Water (OGWDW). The Health and Ecological Criteria Division (HECD) prepares and adapts the health-related supporting documents following guidance from OGWDW. HECD also responds to comments related to its documents that are submitted by the public in response to the Federal Register notice. OGWDW schedules for Regulatory Determination 3 and CCL4 have not yet been finalized.

~~During Option Period 2~~In Work Assignment 2-02, post peer review Health Effects Support Document (HESD) Drafts and responses to peer review comments were completed for 8 chemicals. Changes will be made to the post peer review drafts in response to requests from OGWDW as the Regulatory Determinations are finalized. A ninth HESD was completed and not peer reviewed. Two Health Advisory Documents were drafted that relate to CCL4 or Regulatory Determination has not been finalized.

Summaries of Publications submitted to support CCL4 nominations were prepared as were summaries from literature searches applicable to chemicals that were originally scored for CCL3 based on data from the Registry of Toxic Effects of Chemical Substances (RTECS). The contractor also prepared Table updating the potency and severity information and scores for chemicals from CCL3 using health risk assessments that were not available at the time CCL3 was developed.

QUALITY ASSURANCE

The tasks in this ~~work assignment~~Performance Work Statement (PWS) require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment if necessary. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1, below.

PERFORMANCE WORK STATEMENT (PWS)

TASK 1: Work Plan and Monthly Progress Reports

———Task 1 provides the funding for preparation of the work plan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit the Work Plan in response to this work plan request. The Work Plan shall include a detailed schedule, with deliverables, a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of interest and quality assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the WA Plan. The cost estimate shall include the direct staff costs associated with the level of effort hours as well as any itemized indirect costs, but does not have to be subdivided by Task. The contractor shall prepare monthly reports for the work assignment and include in those reports any adjustments to their quality assurance plan necessitated by unanticipated needs for specialized quality assurance measures.

Task 2: Document Templates

———A template for the HESD documents was prepared under contract # EP-C-07-021 WA 2-09. After the documents are ready for the Regulatory Determination 3 proposal, the contractor shall make revisions to the template so that it is consistent with the proposal drafts.

It is anticipated, that the documents developed as HESD documents will be altered so that they are published as Health Assessment documents for 7 of 8 documents. A new Template will be developed under this work assignment following guidance from OGWDW and all existing documents will be converted to the new template. Written technical directions providing the guidance and boiler plate language for the new Template will be provided by the EPA WAM.

Task 3: Regulatory Determination or CCL4 Literature Searches

———Focused follow-up literature searches for HESD chemicals may be required. Each chemical manager will submit a description of follow-up search needs to the EPA WAM to submit to the contractor as needed. It is estimated that there will be~~Assume at least~~ one (1) minor follow-up search per chemical when determining projected costs.

Task 4: Regulatory Determination or CCL4 Document Retrieval

———The contractor shall retrieve documents from the searches that the EPA Library was not able to obtain. ~~Assume~~ Historically, the retrieval should be ~~for~~ an average of 2 papers per chemical.

Task 5: Revisions to Regulatory Determination HESDs.

———The contractor shall make revisions to the HESDs as they are requested. It is anticipated that the new template will be required for 7 of the 8 peer reviewed HESD documents. Written technical directions for these activities will be provided to the contractor via the EPA WAM once the details for the conversion are known.

Task 6: Response to Peer Reviewer Comments.

———The contractor shall make any revisions to the response to Peer Review documents that are necessitated by the change in Regulatory Determination plans and change in document template. Written technical directions will be provided to the contractor by the EPA WAM. Under the situation where the 9th HESD or the two draft health advisories are peer reviewed, respond to the peer review comments and develop the Response-to Peer Review. Funding for the later of these tasks will be added by amendment if needed.

Task 7: Regulatory Determination and CCL4 Technical Support.

———The Regulatory Determination process requires management briefings, stakeholder's meeting, responses to external comments and Work Group queries. This Task will provide the technical assistance that HECD will require to prepare materials for these occasions. Written technical directions will be provided for each request to the contractor by the EPA WAM. The anticipated activities that will be covered by this task can include:

- Graphics support for PowerPoint presentations (assume requests for two presentations)
- Researching specific questions posed to HECD by the Regulatory Determination or CCL4 Work Groups, OW management and/or OMB (assume one such occurrences per chemical)
- Fact sheet development (assume one occasion which will involve providing health-effects information for inclusion in the OGWDW Regulatory Determination Proposal Fact sheet)
- Providing information summaries or QC for the CCL4 Contaminant Information Sheets.

SCHEDULE AND DELIVERABLES:

Task 1	Two weeks (15 calendar days) after receiving the work assignment.
Task 2	Two months after receiving the Work Plan Request for the HESD Template or one month after receiving the Technical Directions for developing the new health assessment Template.
Task 3	As needed
Task 4	As needed
Task 5	Within three (3) months of development of the new template
Task 6	With two week of receiving EPA WAMs comments on each document after it is converted into the new template.

Task 7	As needed

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United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-02

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-030	06/01/2010 To 05/31/2014 Base Option Period Number 3	Reg Det 3 -CCL4

Contractor: TOXSERVICES LLC

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/01/2013 To 05/31/2014

Comments:
Submit a revised cost estimate for this amendment

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/01/2010 To 05/31/2014 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Joyce Donohue (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1098	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2006	
	FAX Number:	

PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT # 3-02 Amendment 1

TITLE: **Regulatory Determination 3 – CCL4**

WORK ASSIGNMENT MANAGER (WAM):

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Use Address below:
U.S. Environmental Protection Agency
OW/OST/HECD (4304-T)
EPA West-Connecting Wing, Room 5233MM
1301 Constitution Avenue, NW
Washington, DC 20460

PERIOD OF PERFORMANCE: WA Amendment Issuance thru May 31, 2014

SOW TASKS: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

BACKGROUND

Work Assignment 2-02 supports work on documents for Regulatory Determination 3. Although draft documents were completed under work assignment 2-02, the Office of Groundwater and Drinking Water (OGWDW) changed their plans for Regulatory Determination 3. This necessitated converting 7 of the original 8 documents into Health Advisory Document rather that Health Effects Support Documents (HESD) and resulted in major changes to document structure, development of health advisory values not included in the original documents, and in some cases insertion of sections not in the original documents.

PURPOSE OF AMENDMENT: The purpose of this amendment is to provide additional LOE hours for Task 2, 3, 4 and 7 to complete the conversion of the documents into Health Advisories and to continue the work on CCL4 which will begin its review by OMB soon. In addition, the LOE will provide support to (OGWDW) in responding to any questions from the Office of Management and Budget (OMB) or other reviewers of the draft Federal Register Notice, and responding to comments on the CCL4 proposal after its publication. The contractor shall submit a revised cost estimate for this amendment.

Tasks:

Task 2 - Document Templates

Conversion of the original HESDs to Health Advisories required development of a new document template. Some of the template work has been completed, but further changes are necessary because of input from the OGWDW.

Task 3 - Literature Searches

Literature searches will be required in order to support the OGWDW strontium benefits assessment and to investigate whether major new papers have become available for the health advisory chemicals and possibly in order to respond to OMB questions.

Task 4 - Document Revisions

OGWDW has requested extensive revisions to the draft documents because of major changes in the presentation of monitoring data and the addition of new sections to the Health Advisories. The residual funding in the Work Assignment is not sufficient to support the work requested by OGWDW.

Assessment of the toxicological database for some of the CCL4 chemicals, especially those included UCMR 3 monitoring will be initiated once the Regulatory Determination 2 work is complete.

Task 7 – Technical Support

Assessment of the toxicological database for some of the CCL4 chemicals, especially those included UCMR 3 monitoring will be initiated once the Regulatory Determination 2 work is complete.

As the Regulatory Determination 3 and CCL4 Federal Register notices are made ready for publication, OST will be requested to take part in the preparation of responses to comments from OMB. Following publication of the respective Federal Register Notices, OST will be responsible for addressing all comments related to health effects.

OST will be assisting OGWDW in preparing potions of the benefits assessment for strontium that deal with the health impacts of exposure.

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United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-03

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-030	06/01/2010 To 05/31/2014	Health Effects Screening Appro
	Base Option Period Number 3	

Contractor	Specify Section and paragraph of Contract SOW
TOXSERVICES LLC	3.1.2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 07/15/2013 To 05/31/2014

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

Contract Period: 06/01/2010 To 05/31/2014 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name Octavia Conerly	(Signature) (Date)	Branch/Mail Code: Phone Number 202-566-1094 FAX Number:
Project Officer Name Shirley Harrison	(Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name Shirley Harrison	(Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name Sandra Stargardt-Licis	(Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT #3-03

Title: Health Effects Screening Approach for Pharmaceuticals – National Academy of Sciences Follow-up

EPA Work Assignment Manager
Octavia Conerly
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Period of Performance: June 4, 2013 through May 31, 2014

SOW Section: 3.1.2

BACKGROUND

Pharmaceuticals have been discovered in this nation's ambient waters, wastewater, and drinking water at very low levels. EPA has a strategy to respond to this issue, including improving science through research, improving public understanding, identifying partnership opportunities, and taking regulatory action when appropriate. There are thousands of pharmaceuticals on the market today and still more that are approved daily. This creates a challenge for the Agency since most of these compounds do not have environmentally relevant data or publically available health effects data. Therefore, as a part of our strategy, EPA is examining ways to screen a broad range of pharmaceuticals based upon health benchmark indicators, structure similarities, class of compound, etc.

In December 2008, EPA sponsored a National Academy of Sciences (NAS) workshop where experts were brought together to provide input on possible prioritization and risk assessment approaches for pharmaceuticals. This work assignment is follow-up work resulting from the workshop.

Also, due to continued interest in the potential risks to public health caused by the occurrence of pharmaceuticals in sources of drinking water and, in some cases, finished drinking water, four (4) Federal agencies (including the EPA) signed a Memorandum of Understanding agreement which will improve coordination and collaboration on issues related to pharmaceuticals in water. Under this agreement, Federal agencies will share scientific data and information and coordinate potential future research on the presence of pharmaceuticals in water, their sources and potential health effects. In addition, one of the main actions resulting from this agreement is development of a formal interagency workgroup comprised of representatives from the four participating

Federal agencies and other Federal agencies with responsibilities to address issues related to the occurrence of pharmaceuticals in drinking water and sources of drinking water. The workgroup will provide a forum to exchange information on health effects (such as pharmaceutical biological activity and toxicology) and occurrence (sources, fate and transport) of pharmaceuticals in drinking water as well as provide a way to facilitate interagency consultation on implications of research and analyses derived from shared information. Although the direction that the workgroup will take is uncertain, the analyses, reports and data collected under this work assignment could help to facilitate the path of the Federal interagency workgroup's activities. Therefore, the contractor should be prepared to support the EPA WAM when necessary.

In the previous work assignment #2-03 (Option Period 2), a draft paper was developed. During this ~~carryover~~ work assignment in Option Period 3, the draft paper will be finalized and published. It provides a vehicle to further develop and refine a process for screening pharmaceuticals based on health benchmark indicators and applying this process to four pilot groups of pharmaceuticals using health effects data from the Food and Drug Administration (FDA). This process should allow EPA to screen out as well as prioritize groups of compounds.

As part of this work, EPA has evaluated several screening/prioritization approaches and performed calculations of margin of exposure (MOE) values to compare to screening Reference doses (s-RfDs) and screening Maximum Recommended Safe Doses (MRSDs); compared these benchmarks to the third Contaminant Candidate List (CCL3) results for severity and potency attributes; and compared calculations (s-RfD, s-MRSD, MOE) for each of the 4 groups of drugs; and compared these results to other approaches from the peer-reviewed literature. As necessary, EPA will continue to investigate other prioritization approaches to develop a prioritization process for groups of compounds and include this information in the paper.

QUALITY ASSURANCE

The tasks in this performance work statement require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP), which has been provided by the contractor, and assure the quality of the secondary data used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports provided as specified.

~~PERFORMANCE WORK STATEMENT (PWS)~~TASKS

Task 0 - Workplan and Monthly Progress Report

The contractor shall develop a work plan addressing the tasks in this performance work statement. The work plan must include a schedule, staffing plan, level of effort (LOE), and cost estimate, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed, the contractor must include information on plans to manage work and contract costs. All P levels, hours and total will be provided and costs greater than $100.00 must be itemized in detail. The contractor must provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs broken out by the tasks in this WA

Work plan to EPA WAM	~~2 weeks (~~15 calendar days~~)~~ after receipt of work assignment

Task 1 – Revisions to Final Draft Paper (exploring other approaches)

At the EPA WAM's request, the contractor shall explore and summarize screening and prioritization approaches published in the peer-reviewed literature to include in the final draft paper. The contractor shall incorporate the summary(ies) information into the final draft paper for submission to the EPA WAM for review.

Addition of other approaches to final draft paper	3 weeks following EPA WAM's request

Task 2 – Support to Federal Interagency Pharmaceuticals Workgroup

The contractor shall provide occurrence data and other information, upon request from the EPA WAM, to support the pharmaceuticals workgroup. It is anticipated that the workgroup activities will require access to health effects information and other data collected and reports produced as part of this work assignment and may require additional data analyses by the contractor. The scope of workgroup activities will encompass a broad range of topics related to pharmaceuticals in water that may be of interest to any subset of agencies on the workgroup. It is anticipated that the workgroup will not meet more than once quarterly (3 or 4 times/year). Upon request, the contractor shall provide technical support to the EPA WAM with the participation of the workgroup. The EPA WAM shall report workgroup requests (to include requests for previously-collected health effects information and other analyses or data collected; also to include any new analyses within reasonable resource allocations) to the contractor.

Response to workgroup requests	Case-by-case basis. In general, 4 weeks following EPA WAM's request

Task 3 – Publication of Paper

Once the paper has been finalized and undergone an internal EPA/Office of Water final review process, the contractor shall prepare the final paper for submission to peer reviewed journals (may be as many as five (5) all determined by the EPA WAM) and, if accepted, for journal publication. The contractor shall be responsible for preparing the document according to the respective journal's formatting and submission requirements. These requirements will be provided to the contractor by the EPA WAM. If the paper is accepted for publication and if necessary, the EPA WAM will provide review comments from the journal to the contractor. After discussing the comments with the EPA WAM, the contractor shall incorporate comments (as appropriate) and submit the revised paper to the EPA WAM. It is anticipated that this process may include more than one round of comments from the journal resulting in additional rounds of revisions by the contractor.

Submission of revised paper to EPA WAM and/or journal	Dependant upon individual journal's requirements & deadlines

Task 4 – If necessary, Preparation of Materials for Professional Meetings (Society of Toxicology)

The contractor shall prepare a presentation focusing on the screening and prioritization of groups of pharmaceuticals using health effects information and information from the pilot study of 4 groups of pharmaceuticals for the Society of Toxicology (SOT) annual meeting. This task is subject to SOT's acceptance of the abstracts on this material. The contractor shall submit the presentation for the EPA WAM to review. Per the EPA WAM's review, the contractor shall make corrections and prepare the final presentation.

Final presentation to EPA WAM	2 weeks prior to SOT meeting

TRAVEL:

To include two trips to Washington, DC for review of analyses, reports and/or meeting with the interagency pharmaceuticals workgroup and the EPA WAM and others. Also, travel includes one trip to the annual Society of Toxicology meeting. Costs for this travel are included in the IGCE as ODC costs.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-03

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-030	06/01/2010 To 05/31/2014 Base Option Period Number 3	Health Effects for Pharms

Contractor: TOXSERVICES LLC

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/15/2013 To 05/31/2014

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
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Authorized Work Assignment Ceiling

Contract Period: 06/01/2010 To 05/31/2014 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Octavia Conerly (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1094	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
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	FAX Number:	
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2006	
	FAX Number:	

PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT #3-03AMD 1

Title: Health Effects Screening Approach for Pharmaceuticals – National Academy of Sciences Follow-up

EPA Work Assignment Manager
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Period of Performance: WA Amendment Issuance through May 31, 2014

Purpose: The purpose of this amendment is to add additional LOE hours to continue work on Task 2 of this work assignment. Additional hours are needed due to the unanticipated amount of preparation and follow-up for the Pharmaceuticals in Water Interagency workgroup. The EPA WAM and the workgroup held a meeting on Wednesday, February 26, 2014, during which decisions were made regarding workgroup products. Some products required additional gathering of health effects information that was previously unanticipated. The contractor shall submit a revised cost estimate for this amendment.

Task 2 – Support to Federal Interagency Pharmaceuticals Workgroup
The contractor shall provide occurrence data and other information, upon request from the EPA WAM, to support the pharmaceuticals workgroup. It is anticipated that the workgroup activities will require access to health effects information and other data collected and reports produced as part of this work assignment and may require additional data analyses by the contractor. The scope of workgroup activities will encompass a broad range of topics related to pharmaceuticals in water that may be of interest to any subset of agencies on the workgroup. It is anticipated that the workgroup will not meet more than once quarterly (3 or 4 times/year). Upon request, the contractor shall be prepared to support the workgroup. The EPA WAM shall report workgroup requests (to include requests for previously-collected health effects information and other analyses or data collected; also to include any new analyses within reasonable resource allocations) to the contractor.

Response to workgroup requests	Case-by-case basis. In general, 4 weeks following EPA WAM's request

No change to the following Task:
Task 1 – Revisions to Final Draft Paper (exploring other approaches)
Task 3 – Publication of Paper
Task 4 – If necessary, Preparation of Materials for Professional Meetings (Society of Toxicology)

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-030	06/01/2010 To 05/31/2014 Base Option Period Number 3	Cum Risk for Nitrosamines

Contractor: TOXSERVICES LLC

Specify Section and paragraph of Contract SOW: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2013 To 05/31/2014

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/01/2010 To 05/31/2014 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Joyce Donohue (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1098 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-030	06/01/2010 To 05/31/2014	Cum Risk for Nitrosamines
	Base Option Period Number 3	

Contractor: TOXSERVICES LLC

Specify Section and paragraph of Contract SOW: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2013 To 05/31/2014

Comments:

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): [ ]

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/01/2010 To 05/31/2014 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Joyce Donohue (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1098 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT # 3-07

TITLE: Cumulative Risk for Nitrosamines as a Group

WORK ASSIGNMENT MANAGER (WAM): **Joyce Donohue**
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (MC 4304T)
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E-mail- donohue.joyce@epa.gov

For Delivery (FEDEX or UPS)
Use Address below:
U.S. Environmental Protection Agency
OW/OST/HECD (4304-T)
EPA West-Connecting Wing, Room 5233MM
1301 Constitution Avenue, NW
Washington, DC 20460

PERIOD OF PERFORMANCE: June 1, 2013 through May 31, 2014

SOW TASKS: 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

BACKGROUND

The Safe Drinking Water Act, as amended in 1996 (SDWA) requires EPA to publish a Contaminant Candidate List (CCL) of chemicals that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. SDWA also directs EPA to determine whether to regulate at least five contaminants from the CCL every five years; this is known as the Regulatory Determination process. Six nitrosamines are presently being considered as candidates for Regulatory Determination 3. The six nitrosamines are:

- N-nitrosodibutylamine (NDBA)
- N-nitrosodiethylamine (NDEA)
- N-nitrosodimethylamine (NDMA)
- N-nitrosodi-n-propylamine (NDPA)
- N-nitrosomethylethylamine (NMEA)
- N-nitrosopyrolidine (NPYR)

One option is to consider treating these chemicals as a group since all except for NDPA were detected in public drinking water systems during the Unregulated Contaminant Monitoring Rule 2 sample collection and analysis period.

Each of the nitrosamines listed above was carcinogenic in animal studies via a mutagenic mode of action. All six chemical produced reactive electrophiles following CYP P450 oxidation capable of forming adducts with one or more of the DNA bases. One study, Berger et al. (1987), evaluated the tumorigenicity of NDEA, NPYR, and N-nitrosodiethanolamine individually and as a mixture and found the tumor response to be additive. The additivity of the response provides some justification for considering them as a group when they co-occur in drinking water.

~~The work on this work assignment was initiated in Option Period 1. During Option Period 2~~ Under Work Assignment 2-07, ~~-~~the assessment was peer reviewed and finalized. The Office of Groundwater and Drinking Water (OGWDW) plans to issue the cumulative assessment document in conjunction with Regulatory Determination 3. A new methodology document is to be derived from the main document that will allow the systems to use the derived Relative Potency Factors (RFPs) to determine the total cancer risk expressed in units of NDMA equivalents when more than one nitrosamine is present in a monitoring sample.

~~Option Period 3 rollover covers~~This work assignment covers work modifying the cumulative risk document to reflect the Regulatory Determination decisions of the OGWDW plus development of the methodology document. A date for the Regulatory Determination has not yet been selected. ~~Some of activities will be funded at this time and others may be funded by an amendment as their LOE requirements become better defined.~~

QUALITY ASSURANCE

The tasks in this ~~work assignment~~Performance Work Statement (PWS) require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment if necessary. When such a project-specific processes are necessary they should be noted in the work plan and monthly reports.

PERFORMANCE WORK STATEMENT (PWS)

TASK 1: Work Plan and Monthly Progress Reports

————Task 1 provides the funding for preparation of the work plan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

———The contractor shall prepare and submit the Work Plan in response to this PWS request. The Work Plan shall include a detailed schedule, with deliverables, a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of interest and quality assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the Work Plan. The cost estimate shall include the direct staff costs associated with the level of effort hours as well as any itemized indirect costs, but does not have to be subdivided by Task. The contractor shall prepare monthly reports for this work assignment and include in

those reports any adjustments to their quality assurance plan necessitated by unanticipated needs for specialized quality assurance measures. A final QA report will be submitted with the document drafts for public comment.

Task 2: Revision to Post Peer Reviewed Cumulative Risk Document.

———The Contractor shall make revisions to the post-peer review draft of the cumulative risk document following technical directions from the EPA WAM. The technical directions will reflect the alterations to the document outline and format provided to OST by OGWDW

Task 3: Preparation of a Document on use of the RPFs in Determining Cancer Risks for Nitrosamine mixtures

———OST plans to develop a Health Advisory document that can be used by the utilities to determine cancer risks in units of NDMA-equivalents using the nitrosamine RPFs when mixtures of nitrosamines are detected through monitoring. The plans for this document have not yet been established. Once they are completed and approved by OST and OGWDW, the EPA WAM will provide to the contractor via written technical directions.

Task 4: Technical Support.

———This Task will provide the technical assistance that HECD will need to prepare materials derived from the cumulative risk document for occasions such as management briefings, stakeholder meetings, OMB review etc. Written technical directions will be provided for each request to the contractor by the EPA WAM. The anticipated activities that will be covered by this task will include:

- Graphics support for PowerPoint presentations (assume requests for two presentations)
- Researching specific questions posed to HECD by the Regulatory Determination Work Group, OW management and/or OMB (assume two such occurrences per chemical)
- Fact sheet development (assume two occasions, one which will involve providing health-effects information for inclusion in the OGWDW Regulatory Determination Proposal Fact sheet and the other for the mixtures health advisory process).

SCHEDULE AND DELIVERABLES:

Task 1: ~~Two Weeks (15 calendar days)~~Fifteen calendar days after receiving the work assignment

Task 2: To be determined based on the regulatory determination schedule

Task 3: To be determined based on the regulatory determination schedule

Task 4: As needed

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-08

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-030	06/01/2010 To 05/31/2014 Base Option Period Number 3	Six Year Review 3

Contractor: TOXSERVICES LLC

Specify Section and paragraph of Contract SOW: 3.1.1

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/01/2013 To 05/31/2014

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/01/2010 To 05/31/2014 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Octavia Conerly (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1094 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

PERFORMANCE WORK STATEMENT
TOXSERVICES CONTRACT #EP-C-10-030
WORK ASSIGNMENT #3-08

Title: Six Year Review 3 Health Effects Assessment

EPA Work Assignment COR
Octavia Conerly (Room 5233PP)
U.S. Environmental Protection Agency
Office of Science and Technology
EPA West (Customs Building) Connecting Wing
1301 Constitution Ave. NW MC 4304T
Washington, DC 20004
Telephone #: 202-566-1094 FAX #: 202-566-1140
Email: conerly.octavia@epa.gov

Period of Performance: Work Assignment Issuance through May 31, 2014

SOW Section: 3.1.2

BACKGROUND

The 1996 amendments to the Safe Drinking Water Act (SDWA), Section 1412(b)(9), require the United States Environmental Protection Agency (EPA) to review and, if appropriate, revise each existing National Primary Drinking Water Regulation (NPDWR) no less often than every six years. The SDWA Amendments also specify that any revision of a national primary drinking water regulation will maintain or provide for greater protection of public health. The goal of the cyclical review is to determine whether it is appropriate to consider changes (i.e., to "revise" or "take no action") to existing NPDWRs based on changes in health effects or analytical or technological feasibility that have occurred since the regulations were promulgated. In response to this mandate, EPA developed a *Protocol for the Review of Existing National Primary Drinking Water Regulations* (USEPA, 2002a; USEPA, 2003a) based on recommendations of the National Drinking Water Advisory Council (NDWAC, 2000) and input from stakeholders representing a wide variety of interest groups. EPA updated this protocol for the second review effort (USEPA, 2009a). The protocol outlines the approach to be used to review and identify NPDWRs that may warrant revision. The key elements that are considered in the review process are health effects, analytical methods, occurrence and exposure, treatment technology, and other regulatory provisions (e.g., monitoring and reporting requirements). However, this work assignment will focus only on the review of health effects information for a subset of the existing NPDWR chemicals.

The Agency completed its first Six-Year Review in 2003 and the second review in 2009. This work assignment supports the health effects assessment process for the third Six Year Review. As in the second Six Year Review, for this review, the list of chemicals having NPDWRs have been divided into two groups, List A and List B. As in Six Year 2, List A chemicals are those for which EPA, Agency for Toxic Substances/Disease Registry (ATSDR) or National Academy of Science (NAS) assessments are currently in progress or have been completed since January

2008. All remaining chemicals are on List B and each require a literature search beginning January 2008 to present. The List A chemicals that have newly completed assessments since 2008 have been moved to List B. For these List B chemicals, a literature search will be conducted starting from the search cutoff date of the document to the present date. These chemicals require a comprehensive evaluation which will include the evaluation of risk-based values from preferred sources and additional literature.

The contractor shall develop a summary report of findings, similar to the Six Year Review 2 Health Effects Assessment: Summary Report (Attachment 4), for List A and List B chemicals. This summary report will include a table (see example table in Attachment 2) which categorizes List A and List B chemicals using the categories listed in Attachment 2. *(Attachment 2 depicts outcomes from Six Year Review 2)*

The "EPA Protocol for the Review of Existing National Primary Drinking Water Regulations" (Attachment 3), the summary report "Six Year Review 2 Health Effects Assessment: Summary Report" (Attachment 4) and the Federal Register for Six Year Review 2 (Attachment 5) are attached and should be used for reference and background information.

QUALITY ASSURANCE

The tasks in this performance work statement require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must comply with and supplement the contract level quality assurance project plan (QAPP), which has been provided by the contractor, and assure the quality of the secondary data used under this work assignment. In addition QA/QC forms (Appendix A of the QAPP) must be completed for each individual chemical. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports provided as specified.

TASKS

Task 0 - Workplan and Monthly Progress Report

The contractor shall develop a work plan addressing the tasks in this performance work statement. The work plan must include a schedule, staffing plan, level of effort (LOE), and cost estimate, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed, the contractor must include information on plans to manage work and contract costs. All P levels, hours and total will be provided and costs greater than $100.00 must be itemized in detail. The contractor must provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs broken out by the tasks in this WA.

Work plan to EPA WA-COR	15 calendar days after receipt of work assignment

Task 1 – List A Health Assessment Review, Literature Search Strategy, Literature Search and Determination of Potential Critical Studies

The contractor shall review the new assessments for **all List A chemicals that have been moved to List B (see Attachment 1)** which have been determined by EPA as having new assessments (EPA, ATSDR or NAS) completed since January 2008. The contractor shall document any new significant health effects outcomes. Based on the contractor's expert judgment, if it is determined that new health assessment information will significantly affect the current drinking water standard, the contractor shall document this determination.

The contractor shall develop a literature search strategy, for List B chemicals (Attachment 1), which will include the search for reviews/ assessments by the National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS), California EPA (CalEPA), World Health Organization (WHO), European Commission Concise International Chemical Assessment Documents (CICADS), International Programme on Chemical Safety/Environmental Health Criteria (IPCS/EHC), International Agency for Research on Cancer (IARC), Health Canada, Joint Expert Committee on Food Additives (JECFA), and Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Each organization's most recent assessment will be obtained for review when available.
Note: A literature search for EPA, ATSDR and NAS assessments was conducted prior to this work assignment.

Literature searches will be conducted to identify primary literature to supplement the information in the authoritative reviews. The following databases will be searched: TOXLINE, MEDLINE®, Developmental and Reproductive Toxicology (DART®), Chemical Carcinogenesis Research Information System (CCRIS), and Hazardous Substances Data Bank (HSDB).

The contractor shall submit the literature search strategy to the EPA WA-COR for review two weeks following the receipt of the work plan approval. The EPA WA-COR will submit comments on the literature search strategy to the contractor one week following the receipt of the search strategy. The contractor shall incorporate the EPA WA-COR's comments into the search strategy and finalize the strategy one week following receipt of EPA WA-COR's comments.

Following finalization of the strategy, the contractor shall conduct a literature search of peer reviewed publications of health effects information published between the cutoff date of the new assessment to the present for List A chemicals which were moved to List B, and beginning January 2008 to the present for all other List B chemicals, based on the search strategy. The contractor shall include abstracts for each publication in the literature search results for each chemical and list them by publication date (most current date listed first). The contractor shall review each study from the literature search for each chemical, determine whether the results of the study could impact current the Maximum Contaminant Level Goal (MCLG) values, flag these potential critical studies and provide links to pdf copies of these critical studies, and the full literature search results to the EPA WA-COR for review and evaluation of the critical studies.

Draft literature search strategy	2 weeks following EPA WA-COR's approval of the work plan
Final literature search strategy	1 week following receipt of EPA WA-COR's comments

Results of comprehensive literature search (including flagged studies and links to potential critical studies)	4 weeks following approval of search strategy

Task 2 – Development of Draft Six Year Review 3 Health Effects Assessment Summary Report and Summary Table

After receipt of the literature results and critical study review comments from the EPA WA-COR, the contractor shall develop a draft summary table for the List A and B chemicals using Table V-2 (Attachment 2) as the template. In addition, the contractor shall prepare a draft summary report of the outcome of the health effects assessment which describes the rationale for each chemical's (List A and List B) assessment outcome. For formatting purposes, the contractor shall follow the format of the Six Year Review 2 Report Summary (Attachment 4). However, the contractor shall not include sections of the report that are not applicable to the Six Year Review 3 health effects assessment process (if any). The contractor shall include the summary table (formatted after Table V-2) along with a description of the findings for the table's content (as described in the Federal Register Vol.75 No.59 (Attachment 5)) in the summary report. The draft summary table can be submitted to the EPA WA-COR immediately upon its completion. The contractor shall submit the draft summary report to the EPA WA-COR for review and comment.

Draft Summary Table	4-6 weeks after receipt of EPA WA-COR comments
Draft Summary Report	6 weeks after receipt of EPA WA-COR comments

Task 3 – Finalize Six Year Review 3 Health Effects Assessment Summary Report (including Summary Table)

After receipt of the EPA WA-COR's comments on the draft summary report, the contractor shall address the comments and submit a final draft summary report to the EPA WA-COR for final review. Following receipt of the EPA WA-COR's final review comments on the final draft report, the contractor shall address any comments and finalize the report.

Final Draft Summary Report	1 week after receipt of the EPA WA-COR's comments
Final Summary Report	1 week following receipt of the EPA WA-COR's final review

TRAVEL: No required travel is anticipated for this work assignment.

ATTACHMENT 1 (PAGE 1 of 5)

LIST A

Chemicals with health effects assessments (EPA/ATSDR/NAS) that are:

1) Currently in Progress
or
2) Recently Completed (completed since January of 2008)

Preliminary Category 1-7 Status	CHEMICAL	[Organization (Year of latest assessment)]
2	Arsenic, inorganic	EPA/IRIS External Tox Review Draft (2010)
3	Asbestos (fibers >10 micrometers)	EPA/IRIS (1993) EPA/IRIS External Tox Review Draft (2011)
1	Benzo(*a*)pyrene (PAHs)	EPA/IRIS (1994) EPA/IRIS External Tox Review Draft (2013)
3	Chromium VI (as part of total Chromium) No search required for Chromium VI.	EPA/IRIS (III-1998; VI- EPA/IRIS External Tox Review Draft (2010)) (also, VI-EPA/NCEA-IRIS Draft, Status: *FY14*) ATSDR (2012)
3	*o*-dichlorobenzene	EPA/IRIS (1991) EPA/IRIS Draft Tox Review (2003) EPA/IRIS *Track* Re-Assessment Status: *TBD* (EPA/NCEA-Cin)
3	*p*-dichlorobenzene	EPA/IRIS (1991) EPA/IRIS Draft Tox

		Review (2003) **EPA/IRIS *Track* Re-Assessment Status: *TBD* (EPA/NCEA-Cin)**
3	**Di(2-ethylhexyl) adipate (DEHA)**	**EPA/IRIS (1994)** **EPA/IRIS *Track* Re-Assessment Status: TBD**
1	**Di(2-ethylhexyl) phthalate (DEHP)**	**EPA/IRIS (1993)** **EPA/IRIS *Track* Re-Assessment Status: *TBD***
1	**Hexachlorobenzene**	**EPA/IRIS (1996)** **ATSDR Draft Tox Profile for Public Comment (2013)**
1	**Polychorinated biphenyls (PCBs)**	**EPA/IRIS (1997)** **EPA/IRIS *Track* Re-Assessment Status: *TBD* (EPA/NCEA-RTP)** **ATSDR *brief addendum* (2011)**
2	**Uranium**	**EPA/IRIS (1989)** **ATSDR (2013)**

LIST B

Chemicals with no ongoing health effects assessments (EPA/ATSDR/NAS) and completed assessments needing updates from List A [Organization (Year of latest assessment)]

CHEMICAL	[Organization (Year of latest EPA assessment)]
Acrylamide **from List A*	EPA/IRIS (2010) ATSDR (2012)
Alachlor	EPA/IRIS (1993) EPA/OPP RED (1998)
Alpha/photon emitters **from List A*	EPA/ORIA future activity (2006 methods paper; NAS 2006 paper)
Antimony	EPA/IRIS (1991)
Atrazine **from List A*	EPA/IRIS (1993) EPA/OPP RED (2009)
Barium	EPA/IRIS (2005)
Beryllium	EPA/IRIS (1998) NAS (2007, 2008)
Beta/photon emitters **from List A*	EPA/ORIA future activity (2006 methods paper; NAS 2006 paper)
Cadmium **from List A*	EPA/IRIS (1994) ATSDR (2012)
Carbofuran	EPA/IRIS (1987) EPA/OPP RED (2007)
Chlordane **from List A*	EPA/IRIS (1998) ATSDR *brief addendum* (2013)
Chlorobenzene **from List A*	EPA/IRIS (1993) ATSDR *brief addendum* (2013)
Chromium (total) As part of Total Chromium, perform search for Chromium III (Trivalent Chromium) only. No search required for Chromium VI.	EPA/IRIS (III-1998; VI-EPA/IRIS External Tox Review Draft (2010)) (also, VI-EPA/NCEA-IRIS, Status: *FY14*) ATSDR (2012)
cis-1,2-dichloroethylene **from List A*	EPA/IRIS (2010)
trans-1,2-dichloroethylene **from List A*	EPA/IRIS (2010)

Cyanide, free **from List A*	**EPA/IRIS (2010)**
2,4-D (2,4-Dichlorophenoxy Acetic Acid)	**EPA/IRIS (1988) EPA/OPP RED (2005)**
Dalapon (2,2-Dichloropropionic Acid)	**EPA/IRIS (1989)**
1,2-dibromo-3-chloropropane (DBCP)	**EPA/IRIS (1991)**
1,1-dichloroethylene	**EPA/IRIS (2002)**
Dinoseb	**EPA/IRIS (1993)**
Diquat	**EPA/IRIS (1995) EPA/OPP/RED (1995)**
Endothall	**EPA/IRIS (1991) EPA/OPP/RED (2005)**
Endrin	**EPA/IRIS (1993)**
Ethylbenzene **from List A*	**EPA/IRIS (1991) EPA/IRIS *Track* Re-Assessment Status: *TBD* (EPA/NCEA-RTP) ATSDR (2010)**
Epichlorohydrin	**EPA/IRIS (1994)**
Glyphosate	**EPA/IRIS (1993) EPA/OPP/RED (1993)**
Heptachlor	**EPA/IRIS (1993) EPA/OPP/RED (1992)**
Heptachlor epoxide	**EPA/IRIS (1993)**
Hexachlorocyclopentadiene	**EPA/IRIS (2001)**
Lindane (gamma-Hexachlorocyclohexane)	**EPA/IRIS (1993)**
Mercury (inorganic)	**EPA/IRIS (1995) ATSDR *brief addendum* (organic mercury) (2013)**
Methoxychlor **from List A*	**EPA/IRIS (1993) EPA/OPP/RED (2004) ATSDR *brief addendum* (2012)**
Nitrate (measured as nitrogen)	**EPA/IRIS (1991)**
Nitrite (measured as nitrogen)	**EPA/IRIS (1997)**
Oxamyl (vydate)	**EPA/IRIS (1991) EPA/OPP/RED (2007)**
Pentachlorophenol **from List A*	**EPA/IRIS (2010) ATSDR *brief addendum* (2012)**
Picloram	**EPA/IRIS (1992) EPA/OPP/RED (1995)**
Radium (226, 228)	**EPA/ORIA future activity (2006 methods paper; NAS 2006 paper)**
Selenium	**EPA/IRIS (1993)**

Simazine	**EPA/IRIS (1994)** **EPA/OPP/RED (2006)**
Styrene ***from List A***	**EPA/IRIS (1993)** **(also, EPA/NCEA-RTP, Status: *TBD*)** **ATSDR (2010)**
Thallium ***from List A***	**EPA/IRIS (2009)**
2,3,7,8-Tetrachlorodibenzo-p-Dioxin ***from List A***	**EPA/IRIS (2012)** **(also, EPA/NCEA-Cin, Status: *TBD*)**
Toluene	**EPA/IRIS (2005)**
Toxaphene ***recommended for contractor lit review***	**EPA/IRIS (1991)** **ATSDR Draft Tox Profile for Public Comment (2010)**
2,4,5-TP (Silvex; 2,4,5-Trichlorophenoxypropionic Acid)	**EPA/IRIS (1989)**
1,2,4-trichlorobenzene ***recommended for contractor lit review***	**EPA/IRIS (1996)** **ATSDR Draft Tox Profile for class (2010)**
1,1,1-trichloroethane	**EPA/IRIS (2007)**
1,1,2-trichloroethane ***from List A***	**EPA/IRIS (1995)** **ATSDR *brief addendum* (2010)**
Xylenes (total)	**EPA/IRIS (2003)**

ATTACHMENT 2 *(Table will be modified to reflect Six Year 3 results/outcomes)*

Table V-2. Summary of the Outcome of the Six-Year Health Effects Review			
Health Effects Review Category			**Contaminants**
Health Effects Assessment In Process During Information Review Period for the Notice (and not available by the March 1, 2009 cutoff date)	Category 1: MCLG ≥ 0 and MCL based on Analytical Feasibility or standard is a TT		15 Total - acrylamide; alpha particles; benzo(a)pyrene; beta particles; carbon tetrachloride; DEHP; 1,2-dichloroethane; dichloromethane; pentachlorophenol; PCBs; radium; dioxin; tetrachloroethylene; thallium; and trichloroethylene
	Category 2: MCLG = 0 and MCL based on cost-benefit		2 Total – arsenic and uranium
	Category 3: MCLG > 0 and the MCL is set at the MCLG		13 Total – antimony; asbestos; beryllium; cadmium; cyanide; DEHA; 1,2-dichlorobenzene; 1,4-dichlorobenzene; cis-1,2-dichloroethylene; trans-1,2-dichloroethylene; ethylbenzene; fluoride; and styrene
Health Effects Assessment Completed Since Six-Year Review 1	Category 4: New health risk information could lower MCLG/MCL		4 Total – 2,4-D (2005, new data); endothall (2005, new data); toluene (2005, uncertainty factor adjustment); and total xylenes (2003, uncertainty factor adjustment)
	Category 5: New health risk information could raise MCLG/MCL		5 Total – alachlor (2006[1]); barium (2005); diquat (2002[2]); glyphosate (2002[3]); and 1,1,1-trichloroethane (2007, new data)
	Category 6: No new health risk information		2 Total – benzene (2003); EDB (2004)
	Category 7: Awaiting the outcome of emerging information or cancellation decision		3 Total - atrazine[4]; simazine[4]; and carbofuran[5]
Literature Review Only	Health Effects Assessment Completed During Six-Year Review 1	Category 8: New health risk information could lower MCLG/MCL	2 Total – hexachlorocyclopentadiene (2001); and oxamyl (2000)
		Category 9: New health risk information could raise MCLG/MCL	3 Total – 1,1-dichloroethylene (2002); lindane (2002); and picloram (1995)
		Category 10: No new health risk information	3 Total – chlordane (1998), inorganic mercury (1997),and vinyl chloride (2000)
	Category 11: New Information Identified; Potential Nominee for a New Assessment		5 Total – total chromium (hexavalent); nitrate; nitrite; selenium; and 1,2,4-trichlorobenzene
	Category 12: MCLG = 0 No new health risk information		7 Total – DBCP; 1,2-dichloropropane; epichlorohydrin; heptachlor; heptachlor epoxide; hexachlorobenzene; and toxaphene
	Category 13:MCLG > 0 No new health risk information		7 Total – dalapon; dinoseb; endrin; methoxychlor; monochlorobenzene; 2,4,5-TP; and 1,1,2-trichloroethane

1. The 2006 cumulative risk document (USEPA, 2006a) does not present a new assessment; it uses the cancer assessment in the 1998 Reregistration Eligibility Decision (RED; USEPA, 1998a).
2. The 2002 Interim Tolerance Reassessment and Risk Management Decisions (TRED; USEPA, 2002d) does not include a change in risk values, which are those reported in the 1995 RED (USEPA, 1995a).
3. The 2002 TRED (USEPA, 2002a) uses risk values consistent with those reported in the 1993 RED (USEPA, 1993b), with differences only in RfD rounding.
4. Although atrazine and simazine had new health effects assessments completed during the Six-Year Review 2 information period, on October 7, 2009, the Agency announced its intent to re-evaluate the risk assessment for atrazine. Because the simazine assessment is based on atrazine data, simazine was placed in this same category.
5. Although carbofuran had a new health effects assessment completed during the Six-Year Review 2 information period, a recent pesticide cancellation decision could affect the MCLG.